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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,743	01/17/2006	Takashi Maeda	01997.0266	1520

22852 7590 07/27/2007
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,743	Applicant(s) MAEDA ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Request for Continued Examination (RCE) filed July 5, 2007 under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), is acknowledged and accepted.

Claims 1, 4 and 8-13 remain under consideration.

Claims 1, 4 and 8-13 were rejected under 35 U.S.C. 112, second paragraph, in the last Office Action as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. It was asserted the recitation in claims 1 and 4 "wherein an amount of the enema preparation is one tenth as much as the amount used with oral administration" is indefinite. It was unclear whether or not the "amount" refers to the active agent, 6-[2-(3,4-diethoxyphenyl)thiazol-4-yl]pyridine-2-carboxylic acid, or the amount of the preparation.

In response, Applicants urge the amendments to claims 1 and 4 make it clear that it is the claimed thiazole compound or a salt thereof that is the active ingredient in the enema preparation.

Applicants' argument is persuasive. The rejection of record under 35 U.S.C. 112, second paragraph, is withdrawn.

Claims 1 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The claimed enema preparation is a finite entity. Accordingly, while the amount of the active ingredient may be recited as a range, variables in the contemplated

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dosage, such as with respect to a particular patient population, hepatic or renal status, age, gender, etc., render the claims indefinite.

Further, the characterization of glycerol, ethylene glycol, propylene glycol, polyethylene glycol and polypropylene glycol as non-aqueous solvents in claim 11 is confusing.

Clarification is required.

In the last Office Action claims 4-7 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 12 of U.S. Patent No. 6,291,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 in the patent recites the same compound as presently recited in claims 5 and 7 for use in the treatment of Crohn's disease, an inflammatory bowel disease. Intrarectal administration is disclosed in column 10, lines 19-20.

Applicants have not responded further to this rejection. Accordingly, the rejection of record on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 12 of U.S. Patent No. 6,291,487, is maintained.

Claims 1-3 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/424904 in the last Office Action.

Claims 1-6 of copending Application No. 10/424904 are canceled. Accordingly, the provisional rejection of record on the ground of nonstatutory obviousness-type double patenting is moot.

Claims 1-7 remained rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Banan et al., Free Radical Biology & Medicine. It was asserted Banan teaches local administration of the compound OPC-6535, 6-[2-(3,4-diethoxyphenyl)thiazole-4-yl]pyridine-2-carboxylic acid, for use in the treatment of inflammatory bowel diseases, such as ulcerative colitis, in an enema formulation. The compound protects gastrointestinal mucosal integrity against reactive oxygen metabolites (ROM).

Applicants persuasively argue Banan's disclosure fails to teach a method for treating inflammatory bowel disease wherein a dosage that is administered is an amount that is one tenth as much as the amount used with an oral administration and is unexpectedly effective in an animal model of colitis.

Accordingly, the rejection of record of claim 4 under 35 U.S.C. 102(b) as being anticipated by Banan et al., Free Radical Biology & Medicine, is withdrawn. The rejection of record of composition claim 1 is maintained and presently extended to claim 12. An amount of 10 μ M of OPC-6535 was administered in Banan's teaching. The amount of the active ingredient in the claimed enema preparation is hypothetical.

Claims 1, 4 and 8-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chihiro et al., U.S. Patent 6,291,487, in view of Remington's Pharmaceutical Sciences, in the last Office Action. It was asserted Chihiro teaches the administration of 6-[2-(3,4-diethoxyphenyl)thiazole-4-yl]pyridine-2-carboxylic acid for use in the treatment of the inflammatory bowel disease, Crohn's disease. See Example

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27, Table 11, column 29, and claim 11, column 38. Intrarectal administration is disclosed in column 10, lines 19-20. Enema administration is conventional practice in the treatment of Crohn's disease. Although Chihiro fails to teach enema formulations, Remington teaches the preparation of enema formulations with both aqueous and non-aqueous solvent systems. See page 1443, column 2, where water is employed to dissolve the active agent. See column 2 on page 1803, where oil solutions are used as non-aqueous solvents in enema formulations. Because oxidative inflammatory intestinal disorders are characterized by an abnormal mucosal barrier, one skilled in the gastroenterology art would have been motivated to prepare and administer an enema preparation. Such would have been obvious in the absence of evidence to the contrary because it would have been reasonable to expect an enema formulation comprising a known efficacious drug for the treatment of Crohn's disease to provide a local beneficial affect to the disease process.

Applicants argue Chihiro does not teach the amount of the active ingredient used in the claimed enema preparation can be significantly reduced to an extent that could not have been expected.

Applicants' argument is persuasive with respect to the claimed methods for treating inflammatory bowel disease. A reduction of one tenth of the effective oral dosage in an animal model to an effective amount administered via an enema is unexpected.

Accordingly, the rejection of record of claims 4 and 13 under 35 U.S.C. 103 as being unpatentable over Chihiro et al., U.S. Patent 6,291,487, in view of Remington's

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Pharmaceutical Sciences, is withdrawn. The rejection of record of composition claims 1 and 8-12 is maintained. The amount of the active ingredient in the claimed enema preparation is hypothetical.

No claim is allowed.

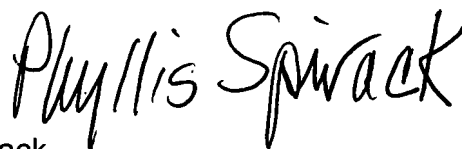
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 21, 2007

Phyllis G. Spivack



PHYLLIS SPIVACK
PRIMARY EXAMINER